K013749 1/2

EndoANCHOR and OpenANCHOR
510(k) Summary of Safety and Effectiveness

Company:
Ethicon Endo-Surgery, Inc.
4545 Creek Rd.
Cincinnati, OH 45242

FEB 11 2002

Contact:
Name: Doug Kentz
Title: Regulatory Affairs Associate II

Date Prepared:
November 12, 2001

Name of Device:
Trade Name: EndoANCHOR and OpenANCHOR Fixation Devices
Classification Name: Stapler, General & Plastic Surgery

Predicate Devices:

- Ethicon Endo-Surgery, Inc. ENDOPATH EMS cleared under K913469 on September 30 1991.
- United States Surgical Corp. AutoSuture™ ProTack™ cleared under K963999 on November 27, 1996.

Device Description:

The EndoANCHOR and OpenANCHOR Fixation Devices are sterile, single patient use instruments that deploy nitinol anchors into prosthetic material and soft tissue for fixation and approximation applications. The nitinol anchors are 5.9 mm long and 6.7 mm wide. The EndoANCHOR fixation device is designed for endoscopic surgical use with a trocar or for open surgical use. Two sizes of the EndoANCHOR Fixation Device are offered: a 3 mm and 5 mm diameter shaft. Both instrument shafts are 301 mm long and contain 20 nitinol anchors. The OpenANCHOR Fixation Device is designed for open surgical use. The instrument has a 132mm long, 3 mm diameter shaft and contains 10 nitinol anchors.

Intended Use:

The EndoANCHOR Fixation Device is intended for fixation of prosthetic material to and approximation of soft tissue in various minimally invasive and open general surgical procedures, such as hernia repair.

The OpenANCHOR Fixation Device is intended for fixation of prosthetic material to and approximation of soft tissue in various open general surgical procedures, such as hernia repair.

Technological Characteristics:

The EndoANCHOR and OpenANCHOR Fixation devices are similar to the predicate devices in that it has the same intended use however these devices deploy an anchor shaped implant made of nitinol for fixation and approximation purposes.

Performance Data

Preclinical testing was performed to ensure the device performs as intended when used according to the instructions for use. Bench and animal testing demonstrated satisfactory performance of the EndoANCHOR and OpenANCHOR Fixation Devices during surgical procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2002

Mr. Doug Kentz, RAC
Senior Regulatory Affairs Associate
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Re: K013749
Trade/Device Name: EndoANCHOR and OpenANCHOR Fixation Devices
Regulation Number: 878.4750, 876.1500
Regulation Name: Implantable staple
Endoscope and accessories
Regulatory Class: II
Product Code: GDW, GCJ
Dated: November 12, 2001
Received: November 13, 2001

Dear Mr. Kentz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K013749

510(k) Number (if known): K013749

Device Name: EndoANCHOR and OpenANCHOR Fixation Devices

Indications for Use:

The EndoANCHOR Fixation Device is intended for fixation of prosthetic material to and approximation of soft tissue in various minimally invasive and open general surgical procedures, such as hernia repair.

The OpenANCHOR Fixation Device is intended for fixation of prosthetic material to and approximation of soft tissue in various open general surgical procedures, such as hernia repair.

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K013749